

Appln No. 10/561,631
Amdt date June 2, 2011
Reply to Office action of January 5, 2011

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Withdrawn) A process for the preparation of isotonic oil emulsions for intravenous administration, comprising the steps of:
 - providing at least one of estrogens and progestagens;
 - providing an oil phase and an aqueous phase;
 - providing an antioxidant;
 - dissolving the at least one of estrogen and progestagen in the oil phase; and
 - emulsifying the oil phase in the aqueous phase; in the presence of an emulsifier.

2. (Currently Amended) A hormone-containing isotonic oil emulsion for intravenous administration comprising:
 - at least one progestagens and at least one estrogen;
 - an oil phase;
 - an antioxidant;
 - an emulsifier; and
 - an aqueous phase;

wherein the at least one progestagens and the at least one estrogen are dissolved in the oil phase prior to being mixed with the aqueous phase and the oil phase comprises oils of marine origin.

3. (Previously Presented) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2, comprising the at least one progestagens and the at least one estrogen in a ratio of from 2:1 to 200:1.

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4. (Previously Presented) The oil emulsion according to claim 2, characterized in that the emulsion contains from 0.005 to 0.5% by weight of the at least one estrogen and from 0.05 to 5% by weight of the at least one progestagen, based on the total composition.

5. (Previously Presented) The oil emulsion according to claim 2, characterized in that the at least one estrogen is estradiol and the at least one progestagen is progesterone.

6. (Previously Presented) The oil emulsion according to claim 2, characterized in that said oil phase comprises medium chain triglycerides (MCT) having a chain length of from 6 to 12 carbon atoms.

7. (Previously Presented) The oil emulsion according to claim 2, characterized by containing from 0.6% to 1.5% by weight of the emulsifier, based on the total composition.

8. (Withdrawn) Use of the isotonic oil emulsion according to any of claims 2 to 7 for preparing a medicament for intravenous administration of estrogen and progestagen for postnatal hormone substitution in premature babies.

9. (Withdrawn) Use of the isotonic oil emulsion according to any of claims 2 to 7 for preparing a medicament for the treatment of neurological damage after strokes.

10. (Withdrawn) A process for hormone substitution in premature babies by using the isotonic oil emulsion according to any of claims 2 to 7.

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11. (Withdrawn) A process for the treatment of neurological damage after strokes by using the isotonic oil emulsion according to any of claims 2 to 7.

12. (Previously Presented) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2; further comprising a co-emulsifier.

13. (Previously Presented) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 12, wherein the co-emulsifier is present in an amount of from 0.005 to 0.1% by weight, based on the total composition.

14. (Previously Presented) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2; wherein the antioxidant comprises tocopherols or tocopherol esters.

15. (Previously Presented) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2; wherein the antioxidant is present in an amount from about 10mg to 1000mg, based on 100g of the oil phase.

16. (Previously Presented) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2; having a pH value from 6.0 to 9.0.

17. (New) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2, wherein the oil phase comprises fish oils.

18. (New) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2, wherein the oil phase further comprises oils of vegetable origin.

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19. (New) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 18, wherein the oil phase further comprises medium-chain triglycerides (MCT).